

104TH CONGRESS
2D SESSION

S. 1898

To protect the genetic privacy of individuals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 24, 1996

Mr. DOMENICI introduced the following bill; which was read twice and referred
to the Committee on Labor and Human Resources

A BILL

To protect the genetic privacy of individuals, and for other
purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This act may be cited as the
5 “Genetic Confidentiality and Nondiscrimination Act of
6 1996”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of
8 this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings and purposes.
Sec. 3. Definitions.

TITLE I—COLLECTION, STORAGE, AND ANALYSIS OF DNA SAMPLES

- Sec. 101. Collection of DNA samples.
- Sec. 102. Genetic analysis of DNA samples.
- Sec. 103. Authorization for collection and storage of DNA samples for genetic analysis.
- Sec. 104. Ownership and destruction of DNA samples.
- Sec. 105. Notice of rights and assurances.

TITLE II—DISCLOSURE OF GENETIC INFORMATION

- Sec. 201. Disclosure of genetic information.
- Sec. 202. Authorization for disclosure of genetic information.
- Sec. 203. Inspection and copying of records containing genetic information.
- Sec. 204. Amendment of records.
- Sec. 205. Disclosures pursuant to compulsory process.

TITLE III—DISCRIMINATION PROHIBITED

- Sec. 301. Discrimination by employers or potential employers.
- Sec. 302. Discrimination by insurers.

TITLE IV—EXCEPTIONS FOR IDENTIFICATION AND COURT- ORDERED GENETIC ANALYSIS

- Sec. 401. Identification of dead bodies.
- Sec. 402. Identification of remains from active-duty military personnel.
- Sec. 403. Identification for law enforcement purposes.
- Sec. 404. Collection and analysis of DNA samples pursuant to court ordered analysis.

TITLE V—RESEARCH ACTIVITIES

- Sec. 501. Research involving genetic analysis.
- Sec. 502. Disclosure of genetic information for research purposes.
- Sec. 503. Exception for DNA samples collected prior to the effective date.

TITLE VI—MINORS

- Sec. 601. Authorization for collection and analysis of DNA from minors.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. Notification of privacy obligations.
- Sec. 702. Transfer of ownership, discontinuance of services.

TITLE VIII.—ENFORCEMENT

- Sec. 801. Civil remedies.
- Sec. 802. Civil penalties and injunctive relief.

TITLE IX—EFFECTIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

- Sec. 901. Effective dates.
- Sec. 902. Applicability.
- Sec. 903. Relationship to other laws.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—Congress finds the following:

3 (1) The DNA molecule contains an individual's
4 genetic information, and this information is written
5 in a code that is being rapidly deciphered,
6 sequenced, and understood.

7 (2) Genetic information is uniquely private and
8 personal information.

9 (3) Genetic information has been misused re-
10 sulting in harm to individuals.

11 (4) The improper use and disclosure of genetic
12 information can lead to significant harm to the indi-
13 vidual, including stigmatization and discrimination.

14 (5) The potential for misuse with respect to ge-
15 netics is tremendous since genetics transcends medi-
16 cine. It has the potential to penetrate many aspects
17 of life including employment, insurance, forensics, fi-
18 nance, education, and even one's self-perception.

19 (6) DNA samples and genetic information
20 should not be collected, stored, analyzed, nor dis-
21 closed without the individual's authorization.

22 (7) A genetic analysis of an individual's DNA
23 provides information not only about an individual,
24 but also about that individual's parents, siblings and
25 children, potentially infringing on individual and
26 family privacy.

1 (8) Because of its unique nature, DNA can be
2 linked to a single identifiable individual, regardless
3 of whether identifiers are limited to a DNA sample.

4 (9) Existing legal protections for genetic infor-
5 mation are inadequate to ensure genetic privacy.

6 (10) Uniform rules for the collection, storage
7 and use of DNA samples and genetic information
8 obtained from such samples are needed both to pro-
9 tect individual privacy and to permit legitimate ge-
10 netic research.

11 (b) PURPOSES.—It is the purpose of this Act to—

12 (1) define the circumstances under which ge-
13 netic information may be created, stored, analyzed,
14 and disclosed;

15 (2) define the rights of individuals and persons
16 with respect to genetic information;

17 (3) define the responsibilities of persons with
18 respect to genetic information;

19 (4) protect individuals from genetic discrimina-
20 tion;

21 (5) establish uniform rules that protect individ-
22 ual genetic privacy and allow the advancement of ge-
23 netic research; and

1 (6) establish effective mechanisms to enforce
2 the rights and responsibilities established under this
3 Act.

4 **SEC. 3. DEFINITIONS.**

5 In this Act:

6 (1) **COLLECTION.**—The term “collection”
7 means obtaining a DNA sample or samples.

8 (2) **COMPULSORY DISCLOSURE.**—The term
9 “compulsory disclosure” means any disclosure of ge-
10 netic information mandated or required by Federal
11 or State law in connection with a judicial, legislative,
12 or administrative proceeding, including, disclosure
13 required by subpoena, subpoena duces tecum, re-
14 quest or notice to produce, court order, or any other
15 method of requiring a person maintaining genetic in-
16 formation to produce genetic information under the
17 criminal or civil discovery laws of any State or under
18 Federal law.

19 (3) **DISCLOSE.**—The term “disclose”, when
20 used with respect to genetic information, means to
21 provide access to the information, but only if such
22 access is provided to a person other than the individ-
23 ual.

24 (4) **DISCLOSURE.**—The term “disclosure”
25 means the act or an instance of disclosing.

1 (5) DNA.—The term “DNA” means
2 deoxyribonucleic acid including mitochondrial DNA,
3 complementary DNA, as well as any DNA derived
4 from ribonucleic acid (RNA).

5 (6) DNA MATCHING.—The term “DNA match-
6 ing” means a scientifically reliable method for char-
7 acterizing and comparing sequences of DNA, and
8 applying a statistical analysis of population fre-
9 quency to determine that if the DNA sequences
10 match, and the probability that the match occurs by
11 chance.

12 (7) DNA SAMPLE.—The term “DNA sample”
13 means any human biological specimen from which
14 DNA is intended to be extracted, or DNA extracted
15 from such specimen.

16 (8) EMPLOYER.—The term “employer” has the
17 same meaning given such term in section 3(d) of the
18 Fair Labor Standards Act of 1938 (29 U.S.C.
19 203(d)).

20 (9) FAMILY.—The term “family” includes an
21 individual’s blood relatives and any legal relatives,
22 including a spouse or adopted child.

23 (10) GENETIC ANALYSIS.—The term “genetic
24 analysis” means extracting genetic information from
25 DNA.

1 (11) GENETIC INFORMATION.—The term “ge-
2 netic information” means the information that may
3 derive from an individual or a family member about
4 genes, gene products, or inherited characteristics.
5 Such term includes DNA sequence information in-
6 cluding that which is derived from the alteration,
7 mutation, or polymorphism of DNA or the presence
8 or absence of a specific DNA marker or markers.

9 (12) INDIVIDUAL.—The term “individual”
10 means the source of the DNA sample, including the
11 body, body parts, or bodily fluids of the individual
12 from whom the DNA sample originated.

13 (13) INDIVIDUAL IDENTIFIER.—The term “in-
14 dividual identifier” means a name, address, social
15 security number, health insurance identification
16 number, or similar information by which the identity
17 of an individual can be determined with reasonable
18 accuracy, either directly or by reference to other
19 available information. Such term does not include
20 characters, numbers, or codes assigned to an individ-
21 ual or a DNA sample that cannot singly be used to
22 identify an individual.

23 (14) INSTITUTIONAL REVIEW BOARD.—The
24 term “Institutional Review Board” means a board
25 established in accordance with section 46.102(g) of

1 title 45, Code of Federal Regulations (1992), as
2 such regulation may from time to time be amended.

3 (15) INSURER.—The term “insurer” means any
4 insurance company, health care service contractor,
5 fraternal benefit organization, insurance agent, third
6 party administrator, insurance support organization
7 or other person subject to regulation under State in-
8 surance laws. Such term includes any managed care
9 organization as well as self-funded health plans and
10 health plans regulated under the Employee Retirement
11 Income Security Act of 1974 (29 U.S.C. 1001
12 et seq.).

13 (16) PERSON.—The term “person” shall in-
14 clude a family, corporation, partnership, association,
15 joint venture, government, governmental subdivision
16 or agency, and other legal or commercial entity.

17 (17) RESEARCH.—The term “research” means
18 systematic scientific (including social science) inves-
19 tigation that includes development, testing, and eval-
20 uation, designed or developed to contribute to origi-
21 nal generalizable knowledge.

22 (18) RESEARCHER.—The term “researcher”
23 means a person who conducts research.

24 (19) SECRETARY.—The term “Secretary”
25 means the Secretary of Health and Human Services.

1 (20) STORAGE.—The term “storage” means re-
2 tention of a DNA sample for any length of time.

3 **TITLE I—COLLECTION, STOR-**
4 **AGE, AND ANALYSIS OF DNA**
5 **SAMPLES**

6 **SEC. 101. COLLECTION OF DNA SAMPLES.**

7 (a) REQUIREMENT OF WRITTEN AUTHORIZATION.—
8 Except as provided in sections 401, 402, 403, and 404,
9 no person may collect or cause to be collected a DNA sam-
10 ple for genetic analysis without the written authorization
11 of the individual.

12 (b) REQUIRED INFORMATION.—Prior to the collec-
13 tion of a DNA sample from an individual for genetic anal-
14 ysis, the person collecting the sample or causing the sam-
15 ple to be collected shall verbally inform the individual—

16 (1) that consent to or refusal of the collection
17 or taking of the DNA sample is voluntary;

18 (2) that consent to or refusal of genetic analysis
19 is voluntary;

20 (3) of the information that can reasonably be
21 expected to be derived from the genetic analysis;

22 (4) of the uses, if any, that the individual will
23 be able to make of the information derived from the
24 genetic analysis;

1 (5) of the uses, if any, that the person will
2 make of the information derived from the genetic
3 analysis;

4 (6) of the right to inspect records that contain
5 information derived from the genetic analysis;

6 (7) of the right to have the DNA sample de-
7 stroyed;

8 (8) of the right to revoke consent to the genetic
9 analysis at any time prior to the commencement of
10 the genetic analysis;

11 (9) that the genetic analysis may result in in-
12 formation about the individual's family which may
13 not be known to such relatives but could be impor-
14 tant, and if so the individual should consider wheth-
15 er or not to share that information with relatives;

16 (10) of the existence and protections afforded
17 by this Act; and

18 (11) of the availability of optional genetic and
19 psychological counseling.

20 **SEC. 102. GENETIC ANALYSIS OF DNA SAMPLES.**

21 (a) GENETIC ANALYSIS PROHIBITED WITHOUT AU-
22 THORIZATION.—Except as provided in sections 401, 402,
23 403, and 404, genetic analysis of a DNA sample is prohib-
24 ited unless specifically authorized in writing by the individ-
25 ual.

1 (b) ASCERTAINMENT OF AUTHORIZATION.—No per-
 2 son may analyze a DNA sample without ascertaining that
 3 written authorization for the genetic analysis has been ob-
 4 tained.

5 **SEC. 103. AUTHORIZATION FOR COLLECTION AND STOR-**
 6 **AGE OF DNA SAMPLES FOR GENETIC ANALY-**
 7 **SIS.**

8 (a) WRITTEN AUTHORIZATION.—To be valid, the au-
 9 thorization required by sections 101 and 102 shall comply
 10 with each of the following:

11 (1) WRITING.—The authorization must be in
 12 writing, signed by the individual, and dated on the
 13 date of such signature.

14 (2) COLLECTOR IDENTIFIED.—The authoriza-
 15 tion must identify the person who collects the DNA
 16 sample or causes the DNA sample to be collected.

17 (3) COLLECTION DESCRIBED.—The authoriza-
 18 tion must state the exact bodily source from and the
 19 manner in which the DNA sample is to be collected.

20 (4) AUTHORIZED USE.—The authorization must
 21 include a description of all authorized uses of the
 22 DNA sample.

23 (5) STATEMENT REGARDING STORAGE AFTER
 24 COMPLETION OF ANALYSIS.—The authorization
 25 must indicate whether or not the individual permits

1 the sample to be maintained or stored after the
2 analysis is completed.

3 (6) STATEMENT REGARDING USES OF DNA SAM-
4 PLES FOR RESEARCH OR COMMERCIAL PURPOSES.—

5 The authorization must include a provision that en-
6 ables the individual to allow the uses of the DNA
7 sample for purely academic research and a separate
8 provision that gives specific authorization for com-
9 mercial uses.

10 (b) RETENTION OF AUTHORIZATION.—The author-
11 ization for the collection, storage and analysis of a DNA
12 sample shall be retained for the period during which the
13 DNA sample is retained.

14 (c) COPY.—A copy of the authorization shall be pro-
15 vided to the individual.

16 **SEC. 104. OWNERSHIP AND DESTRUCTION OF DNA SAM-**
17 **PLES.**

18 (a) OWNERSHIP OF THE DNA SAMPLE.—A DNA
19 sample is the property of the individual.

20 (b) RIGHT TO ORDER DESTRUCTION OF THE DNA
21 SAMPLE.—Except when a DNA sample has been collected
22 pursuant to section 402, 403, or 404, the individual shall
23 have the right to order the destruction of the DNA sam-
24 ple.

1 (c) ROUTINE DESTRUCTION OF SAMPLES.—A DNA
2 sample shall be destroyed on completion of genetic analy-
3 sis unless the individual has directed otherwise in writing.

4 **SEC. 105. NOTICE OF RIGHTS AND ASSURANCES.**

5 A person who collects or stores DNA samples for ge-
6 netic analysis shall provide the individual prior to the col-
7 lection, storage, or analysis of the DNA sample, and any
8 other person upon request, with a notice of rights and as-
9 surances that contains the following information and as-
10 surances:

11 (1) That a DNA sample will only be used as
12 authorized in the written authorization.

13 (2) That a DNA sample is the property of the
14 individual.

15 (3) That the individual has the right to order
16 the destruction of the DNA sample at any time.

17 (4) That the DNA sample will be destroyed
18 upon the completion of the analysis unless the indi-
19 vidual has previously directed otherwise in writing.

20 (5) That the individual can designate another
21 person as the one authorized to make decisions re-
22 garding the DNA sample after the death of the indi-
23 vidual, and if any person is so designated, that the
24 individual should notify the facility in which the
25 DNA sample is stored.

1 (6) That the individual has the right to examine
2 records containing genetic information, to obtain
3 copies of such records, and to request correction or
4 amendment of such records.

5 (7) That researchers may be granted access to
6 a DNA sample solely for research purposes and only
7 if specifically authorized by the individual.

8 (8) That the collection, storage and analysis of
9 the DNA sample and the genetic information derived
10 from the analysis is protected by this Act, and that
11 anyone whose rights under this Act have been vio-
12 lated can seek civil remedies, including damages and
13 attorney's fees as provided for in this Act.

14 (9) That optional genetic and psychological
15 counseling are available.

16 **TITLE II—DISCLOSURE OF** 17 **GENETIC INFORMATION**

18 **SEC. 201. DISCLOSURE OF GENETIC INFORMATION.**

19 (a) REQUIREMENT OF WRITTEN AUTHORIZATION.—
20 Except as provided in sections 205 and 502, no person
21 who, in the ordinary course of business, practice of a pro-
22 fession, or rendering of a service, creates, stores, receives
23 or furnishes genetic information may disclose by any
24 means of communication genetic information except in ac-

1 cordance with a written authorization as provided for in
2 section 202.

3 (b) REDISCLOSURE PROHIBITED.—Redisclosure of
4 genetic information which has been disclosed to any per-
5 son pursuant to a valid written authorization is prohibited.

6 **SEC. 202. AUTHORIZATION FOR DISCLOSURE OF GENETIC**
7 **INFORMATION.**

8 (a) WRITTEN AUTHORIZATIONS.—To be valid, an au-
9 thorization for disclosure of genetic information shall com-
10 ply with of the following:

11 (1) WRITING.—The authorization must be in
12 writing, signed by the individual and dated on the
13 date of such signature.

14 (2) PERSON MAKING DISCLOSURE IDENTI-
15 FIED.—The authorization must identify the person
16 permitted to make the disclosure.

17 (3) INFORMATION DESCRIBED.—The authoriza-
18 tion must describe the specific genetic information to
19 be disclosed.

20 (4) RECIPIENT IDENTIFIED.—The authoriza-
21 tion must identify the person to whom the informa-
22 tion is to be disclosed.

23 (5) PURPOSE DESCRIBED.—The authorization
24 must describe the purpose for which the disclosure
25 is being made.

1 (6) EXPIRATION DATE.—The authorization
2 must state the date upon which the authorization
3 will expire, which in no event shall be longer than
4 30 days after the date of the authorization.

5 (7) REVOCATION STATEMENT.—The authoriza-
6 tion must include a statement that the authorization
7 is subject to revocation at any time before the disclo-
8 sure is actually made or the individual is made
9 aware of the details of the genetic information.

10 (b) COPY.—A copy of the authorization shall be pro-
11 vided to the individual.

12 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-
13 TION.—An individual may revoke or amend the authoriza-
14 tion, in whole or in part, at any time.

15 (d) IDENTIFICATION OF INFORMATION AS PRO-
16 TECTED BY LAW.—Each disclosure made with the written
17 authorization described in subsection (a) shall be accom-
18 panied by the following written statement:

19 “This information has been disclosed to you from
20 confidential records protected under the Genetic Confiden-
21 tiality and Nondiscrimination Act of 1996 and any further
22 disclosure of the information without specific authoriza-
23 tion is prohibited.”.

24 (e) EFFECT OF GENERAL AUTHORIZATION FOR RE-
25 LEASE OF MEDICAL RECORDS.—A general authorization

1 for the release of medical records or medical information
2 shall not be construed as an authorization for disclosure
3 of genetic information. With respect to medical records
4 that contain genetic information, the requirements for dis-
5 closure of genetic information under this section must be
6 complied with.

7 **SEC. 203. INSPECTION AND COPYING OF RECORDS CON-**
8 **TAINING GENETIC INFORMATION.**

9 (a) INSPECTION OF RECORDS.—Except as provided
10 in section 501(c)(2) and 501(f), a person who maintains
11 genetic information shall, upon written request, permit the
12 individual to inspect records containing genetic informa-
13 tion and shall provide a copy of any such records upon
14 request of the individual.

15 (b) RESPONSE TO REQUEST EXAMINATION AND
16 COPYING OF INFORMATION.—Upon receipt of a written
17 request from an individual to inspect or copy all or part
18 of records containing genetic information, a person as
19 promptly as required under the circumstances, but in no
20 event later than 90 business days after receiving the re-
21 quest, shall make the information available to the individ-
22 ual for inspection during regular business hours or provide
23 a copy, if requested, to the individual.

24 (c) EXPLANATION OF TERMS AND CODES.—A person
25 shall provide an explanation of terms and any code or ab-

1 breviations used in records containing the genetic informa-
 2 tion upon the request of the individual.

3 (d) FEE.—A person may charge a reasonable fee, not
 4 to exceed the person's actual duplication cost, for copies
 5 of records which are provided under this section.

6 **SEC. 204. AMENDMENT OF RECORDS.**

7 (a) IN GENERAL.—Not later than 90 days after the
 8 receipt of a written request by an individual to amend in
 9 whole or in part any record containing genetic informa-
 10 tion, a person who maintains records containing such ge-
 11 netic information shall—

12 (1) make the amendment requested;

13 (2) inform the individual that the amendment
 14 has been made;

15 (3) make reasonable efforts to inform any per-
 16 son to whom the unamended portion of the informa-
 17 tion was previously disclosed of the amendment that
 18 has been made; and

19 (4) at the request of the individual, make rea-
 20 sonable efforts to inform any known source of the
 21 unamended portion of the information about the
 22 amendment that has been made.

23 (b) REASONS FOR REFUSAL AND REVIEW PROCE-
 24 DURES.—If an amendment is refused under subsection

1 (a), the person maintaining the records shall inform the
2 individual of—

3 (1) the reasons for the refusal of the person to
4 make the amendment;

5 (2) the procedures for further review of such re-
6 fusal; and

7 (3) the individual's right to file with the person
8 a concise statement setting forth the requested
9 amendment and the individual's reasons for dis-
10 agreeing with the refusal of the person to make the
11 amendment.

12 With respect to a concise statement filed under paragraph
13 (3), such statement shall be made part of the record.

14 (c) STANDARDS FOR AMENDMENT.—A person main-
15 taining records containing genetic information shall
16 amend such information in accordance with a request
17 made under subsection (a) if such information is not accu-
18 rate or complete for the purposes for which such informa-
19 tion may be used or disclosed by the person.

20 (d) STATEMENT OF DISAGREEMENT.—After an indi-
21 vidual has filed a statement of disagreement under sub-
22 section (b)(3), the person, in any subsequent disclosure
23 of the disputed portion of the information, shall include
24 a copy of the individual's statement and may include a

1 statement of the reasons for not making the requested
2 amendment.

3 **SEC. 205. DISCLOSURES PURSUANT TO COMPULSORY**
4 **PROCESS.**

5 (a) PROCEEDINGS IN WHICH AVAILABLE.—No per-
6 son who maintains genetic information may be compelled
7 to disclose such information pursuant to a request for
8 compulsory disclosure in any judicial, legislative, or ad-
9 ministrative proceeding, unless—

10 (1) the request for compulsory disclosure is in
11 accordance with section 404;

12 (2) the individual whose genetic information is
13 requested is a party to the proceeding and the ge-
14 netic information is at issue; or

15 (3) the genetic information is for use in a law
16 enforcement proceeding or investigation in which the
17 person maintaining the information is the subject or
18 party.

19 (b) NOTICE.—If genetic information is sought under
20 subparagraph (2) of subsection (a), or in a proceeding or
21 investigation pursuant to subparagraph (3) of subsection
22 (a), the person requesting compulsory disclosure shall
23 serve upon the person maintaining the genetic informa-
24 tion, and upon the individual, or on the individual's attor-
25 ney, the original or a copy of the compulsory disclosure

1 request at least 30 days prior to the date on which the
2 compulsory disclosure is requested, and a statement of the
3 right of the individual, and of the person maintaining the
4 genetic information, to have any objections to such com-
5 pulsory disclosure heard by such court or governmental
6 agency prior to the issuance of an order for such compul-
7 sory disclosure, and the procedure to be followed to have
8 any such objections heard. Such service shall be made by
9 certified mail, return receipt requested, or by hand deliv-
10 ery, in addition to any form of service required by applica-
11 ble State or Federal law.

12 (c) CERTIFICATION.—Service of compulsory process
13 or discovery requests upon a person maintaining genetic
14 information shall be accompanied by a written certifi-
15 cation—

16 (1) signed by the person seeking to obtain the
17 genetic information or his or her authorized rep-
18 resentative;

19 (2) identifying at least one paragraph of sub-
20 section (a) under which compulsory process or dis-
21 covery is being sought; and

22 (3) that states, in the case of information
23 sought under paragraph (2) or (3) of subsection (a),
24 that the requirements under subsection (b) for no-
25 tice have been met.

1 The signature of a person on the certification shall be
2 valid only if the person, at the time of signing, reasonably
3 believed that the paragraph of subsection (a) that is iden-
4 tified in the certification provides an appropriate basis for
5 the use of discovery or compulsory process. A copy of the
6 written certification shall be maintained as a permanent
7 part of the records of genetic information.

8 (d) STANDARD FOR ISSUANCE OF ORDER.—An order
9 under this section may only be entered by a court of com-
10 petent jurisdiction after a hearing and determination that
11 good cause exists. To make such determination the court
12 must find that—

13 (1) other ways of obtaining the genetic informa-
14 tion are not available or would not be effective; and

15 (2) there is a compelling need for the genetic
16 information which outweighs the potential harm to
17 the privacy interest of the subject of the informa-
18 tion.

19 (e) CONTENT OF ORDER.—An order under this sec-
20 tion which authorizes disclosure of genetic information
21 shall—

22 (1) limit disclosure to those parts of records
23 containing such information which are essential to
24 fulfill the objective of the order;

1 (2) limit disclosure to those persons whose need
2 for the information is the basis of the order;

3 (3) require the deletion of individual identifiers
4 from any documents made available to the public;
5 and

6 (4) include such other measures as are nec-
7 essary to limit disclosure for the protection of the
8 subject of the information including sealing from
9 public scrutiny the record or any portion of the
10 record of any proceeding for which disclosure of the
11 information has been ordered.

12 **TITLE III—DISCRIMINATION** 13 **PROHIBITED**

14 **SEC. 301. DISCRIMINATION BY EMPLOYERS OR POTENTIAL** 15 **EMPLOYERS.**

16 (a) IN GENERAL.—An employer may not seek to ob-
17 tain, obtain or use the genetic information of an employee
18 or a prospective employee, or require the collection of a
19 DNA sample of an employee or prospective employee for
20 analysis to distinguish between, discriminate against, or
21 restrict any right or benefit otherwise due or available to
22 the employee or prospective employee.

23 (b) ENFORCEMENT.—The powers, remedies, and pro-
24 cedures set forth in sections 705 through 709 of the Civil
25 Rights Act of 1964 shall be the powers, remedies, and pro-

cedures applicable under this section to any person alleging a violation of this section.

SEC. 302. DISCRIMINATION BY INSURERS.

(a) IN GENERAL.—An insurer offering a policy or plan may not—

(1) terminate, restrict, limit, or otherwise apply conditions to the coverage of an individual or family member under the policy or plan, or restrict the sale of the policy or plan to an individual or family member;

(2) cancel or refuse to renew the coverage of an individual or family member under the policy or plan;

(3) deny coverage or exclude an individual or family member from coverage under the policy or plan;

(4) impose a rider that excludes coverage for certain benefits or services under the policy or plan;

(5) establish differentials in premium rates or cost sharing for coverage under the policy or plan; or

(6) otherwise discriminate against an individual or family member in the provision of insurance;

on the basis of any genetic information concerning an individual or family member or on the basis of an individual's

1 or family member's request for or receipt of genetic serv-
 2 ices.

3 (b) PROHIBITION ON TESTING OR QUESTIONING.—

4 An insurer may not require an applicant for coverage
 5 under the policy or plan, or an individual or family mem-
 6 ber who is presently covered under a policy or plan, to
 7 be the subject of a genetic test or to be subjected to ques-
 8 tions relating to genetic information.

9 (c) DISCLOSURE.—An insurer shall, in the applica-
 10 tion or enrollment information provided by the insurer
 11 concerning a policy or plan, provide an applicant or en-
 12 rollee with a written statement disclosing the rights of the
 13 applicant or enrollee under this Act. Such statement shall
 14 be in a form and manner that is noticeable to and under-
 15 standable by an average applicant or enrollee.

16 (d) ENFORCEMENT.—

17 (1) PLANS OTHERS THAN EMPLOYEE WELFARE
 18 BENEFIT PLANS.—The requirements established
 19 under subsections (a), (b), and (c) shall be enforced
 20 by the State insurance commissioner for the State
 21 involved or the official or officials designated by the
 22 State, except that in no case shall a State enforce
 23 such requirements as they relate to employee welfare
 24 benefit plans (as defined in section 3 of the Em-
 25 ployee Retirement Income Security Act of 1974).

1 (2) EMPLOYEE WELFARE BENEFIT PLANS.—

2 With respect to employee welfare benefit plans, the
3 Secretary shall enforce the requirements established
4 under subsections (a), (b), and (c) in the same man-
5 ner as provided for under sections 502, 504, 506,
6 and 510 of the Employee Retirement Income Secu-
7 rity Act of 1974 (29 U.S.C. 1132, 1134, 1136, and
8 1140).

9 **TITLE IV—EXCEPTIONS FOR**
10 **IDENTIFICATION AND COURT-**
11 **ORDERED GENETIC ANALYSIS**

12 **SEC. 401. IDENTIFICATION OF DEAD BODIES.**

13 Notwithstanding any other provision of this Act, a
14 person may provide access to a DNA sample, or to data
15 derived from DNA matching, to assist in the identification
16 of a dead body if the analysis of any DNA sample or data
17 is limited only to that which is necessary to determine the
18 identity of the dead body.

19 **SEC. 402. IDENTIFICATION OF REMAINS FROM ACTIVE-**
20 **DUTY MILITARY PERSONNEL.**

21 (a) IN GENERAL.—Notwithstanding any other provi-
22 sion of this Act, the United States Armed Forces may—
23 (1) collect, store, or analyze a DNA sample
24 from an active-duty member only for the purposes of
25 the identification of remains; and

1 (2) disclose DNA matching information from
2 active-duty members only for the purposes of the
3 identification of remains.

4 (b) DESTRUCTION.—A DNA sample shall be de-
5 stroyed upon the request of the individual at time of his
6 or her discharge.

7 **SEC. 403. IDENTIFICATION FOR LAW ENFORCEMENT PUR-**
8 **POSES.**

9 Nothing in this Act shall be construed to prohibit
10 Federal, State or local law enforcement authorities from
11 collecting, storing or marking DNA samples, if—

12 (1) the collection, storage and marking is au-
13 thorized under Federal or State law;

14 (2) the collection, storage and marking is lim-
15 ited to the purpose of DNA matching in criminal in-
16 vestigations;

17 (3) access to such DNA samples is limited to
18 authorized law enforcement agencies, prosecutors,
19 defense counsel, defendants, accused individuals,
20 suspects, and their authorized agents; and

21 (4) such authorities have probable cause to col-
22 lect, store, or mark a sample.

1 **SEC. 404. COLLECTION AND ANALYSIS OF DNA SAMPLES**

2 **PURSUANT TO COURT ORDERED ANALYSIS.**

3 Nothing in this Act shall be construed to prohibit
4 court ordered paternity testing in civil actions to deter-
5 mine paternity.

6 **TITLE V—RESEARCH ACTIVITIES**

7 **SEC. 501. RESEARCH INVOLVING GENETIC ANALYSIS.**

8 (a) CONDITIONS FOR A GENETIC ANALYSIS.—Except
9 as provided in section 503, no DNA sample shall be ana-
10 lyzed as part of a research project unless an Institutional
11 Review Board has determined that—

12 (1) use of DNA samples is essential to the re-
13 search project;

14 (2) the potential benefit of the research project
15 outweighs the potential risks to the subjects includ-
16 ing psychosocial risks and intrusion into the privacy
17 of the subjects that would result from genetic analy-
18 sis of DNA samples; and

19 (3) the research protocol—

20 (A) contains adequate safeguards to pro-
21 tect against disclosure of genetic information
22 that is generated by the research;

23 (B) requires that research subjects will be
24 given the applicable information required under
25 section 101 in addition to meeting the informed
26 consent requirements contained in section

1 46.116 of title 45, Code of Federal Regulations
2 (1992) as such regulation may from time to
3 time be amended;

4 (C) requires the written authorization of
5 research subjects that complies with the appli-
6 cable requirements of section 103, and that de-
7 scribes the protocol and the intended uses;

8 (D) prohibits inclusion of research records
9 in medical records unless the individual author-
10 izes such inclusion in writing; and

11 (E) with respect to protocols involving the
12 use of DNA samples from individuals deceased
13 prior to the effective date of this Act, provides
14 a method for disclosing the risk associated with
15 genetic information, which in reasonable medi-
16 cal judgment can be effectively ameliorated,
17 prevented, or treated, to an individual's family
18 members, such method to take into account
19 that family members have the right to refuse
20 learning of any genetic information.

21 Additionally, the researcher or the researcher's institution
22 is responsible for any fees or costs associated with the dis-
23 closure, including for optional genetic or psychological
24 counselling.

1 (b) SAFEGUARDS AGAINST DISCLOSURES OF GE-
 2 NETIC INFORMATION.—For purposes of paragraph (3)(A)
 3 of subsection (a), adequate safeguards against disclosure
 4 of genetic information, at a minimum, include—

5 (1) obtaining a certificate of confidentiality
 6 from the Secretary as provided for in section 301(d)
 7 of the Public Health Service Act (42 U.S.C. 241(d));

8 (2) ensuring that research subjects will not be
 9 identifiable in any report or publication which re-
 10 sults from the research; and

11 (3) having procedures to remove or destroy at
 12 the earliest opportunity consistent with the purposes
 13 of the project, any individual identifiers.

14 (c) FURTHER LIMITATIONS ON RESEARCH INVOLV-
 15 ING INDIVIDUALS UNDER 18.—With respect to an individ-
 16 ual who is under 18 years of age, no research shall be
 17 conducted on DNA samples unless—

18 (1) a parent or guardian is given the applicable
 19 information required under section 101;

20 (2) a parent or guardian executes an authoriza-
 21 tion that meets the applicable requirements of sec-
 22 tion 103 and which specifically states that the par-
 23 ent or guardian understands and agrees that unless
 24 the analysis reveals a genetic condition which in rea-
 25 sonable medical judgment can only be effectively

1 ameliorated, prevented, or treated while the individ-
2 ual is under 18 years of age, the results of the anal-
3 ysis will not be disclosed to the parent or guardian
4 of the individual; and

5 (3) any provisions for soliciting the assent of
6 minors as contained in section 46.408 of title 45,
7 Code of Federal Regulations, which the Institutional
8 Review Board determines to be applicable are met.

9 (d) DESTRUCTION OF DNA SAMPLES OR IDENTIFI-
10 ERS.—In the absence of a specific authorization to main-
11 tain a DNA sample, DNA samples collected, stored or
12 analyzed in connection with a research project shall be de-
13 stroyed upon completion of the project or withdrawal of
14 the individual from the project, whichever occurs first.

15 (e) PEDIGREE ANALYSIS AND FAMILY LINKAGE
16 STUDIES.—When a research project includes genetic anal-
17 ysis of family members for pedigree analysis or linkage
18 analysis—

19 (1) the Institutional Review Board, in addition
20 to making the determinations required in subsection
21 (a), shall also require that to the maximum extent
22 practicable, separate records are maintained on each
23 subject; and

1 (2) subjects, prior to their participation, and in
 2 addition to the disclosures required by section 101,
 3 shall be—

4 (A) informed that one risk of their partici-
 5 pation is that other family members may learn
 6 genetic information about themselves;

7 (B) informed of what will be done with
 8 records and data generated during the project;
 9 and

10 (C) informed that the project may deter-
 11 mine that some members of their family are not
 12 genetic relatives.

13 (f) SUBJECTS RIGHT TO OBTAIN INFORMATION.—
 14 When complying with the provisions of section 203, no
 15 person shall provide an individual in the pedigree with ge-
 16 netic information about any individual in the pedigree
 17 without that individual's authorization.

18 **SEC. 502. DISCLOSURE OF GENETIC INFORMATION FOR RE-**
 19 **SEARCH PURPOSES.**

20 (a) IN GENERAL.—Any person who, in the ordinary
 21 course of business, practice of a profession, or rendering
 22 of a service, stores or maintains genetic information is
 23 prohibited from allowing access to such information to re-
 24 searchers unless—

1 (1) an Institutional Review Board has approved
2 the conduct of the research program or study; and
3 (2) the individual has specifically consented to
4 the access or disclosure of such information in an
5 authorization that meets the requirements of section
6 202.

7 Such information should be provided in a coded form with
8 all individual identifiers removed.

9 (b) LIMITED ACCESS FOR STATISTICAL USE.—Not-
10 withstanding the provisions of subsection (a), a person
11 who stores or maintains genetic information may grant ac-
12 cess to such information solely for the purpose of inspec-
13 tion or review of records containing the information if—

14 (1) the inspection or review is for the purpose
15 of compiling data for statistical or epidemiological
16 studies and genetic information is not to be copied,
17 removed from the records, or redisclosed in any way;
18 and

19 (2) the person conducting the inspection or re-
20 view certifies in writing—

21 (A) that the limitations in paragraph (1)
22 will be complied with;

23 (B) to knowledge of their liability for viola-
24 tions of this Act; and

1 (C) that the person has complied with sec-
 2 tions 101 and 103.

3 **SEC. 503. EXCEPTION FOR DNA SAMPLES COLLECTED**
 4 **PRIOR TO THE EFFECTIVE DATE.**

5 Notwithstanding the provisions of section 501, a
 6 DNA sample that was collected from an individual prior
 7 to the effective date of this Act may be analyzed as part
 8 of a research project under a protocol approved by an In-
 9 stitutional Review Board, if such project—

10 (1) withdraws or destroys the DNA sample if
 11 the individual makes a written request within 3
 12 years of the effective date of this Act; and

13 (2) except as provided under section 502, dis-
 14 closes genetic information only with the authoriza-
 15 tion of—

16 (A) the individual; or

17 (B) a member of the family of the individ-
 18 ual if the individual is deceased.

19 **TITLE VI—MINORS**

20 **SEC. 601. AUTHORIZATION FOR COLLECTION AND ANALY-**
 21 **SIS OF DNA FROM MINORS.**

22 (a) IN GENERAL.—Except as provided in section
 23 501(c), the DNA sample of an individual who is under
 24 18 years of age shall not be collected, stored, or analyzed
 25 to determine the existence of a risk from genetic informa-

1 tion that does not in reasonable medical judgment produce
 2 signs or symptoms of disease before the age of 18, un-
 3 less—

4 (1) there is an effective intervention that will
 5 prevent or delay the onset or ameliorate the severity
 6 of the disease; and

7 (2) the intervention is initiated before the indi-
 8 vidual reaches the age of 18; and

9 (3) the individual's parent or guardian has re-
 10 ceived the disclosures required by section 101 and
 11 has executed a written authorization which meets
 12 the requirements of section 103 and which also lim-
 13 its the uses of such analysis to those permitted by
 14 this section.

15 (b) DESTRUCTION OF DNA SAMPLES OF INDIVID-
 16 UALS UNDER 18.—An individual's parent or guardian
 17 may, on behalf of an individual who is under 18 years of
 18 age, order the destruction of a DNA sample collected pur-
 19 suant to subsection (a).

20 (c) PROHIBITION ON USE OF NEWBORN SCREEN-
 21 ING.—In no event shall any DNA collected, stored, or ana-
 22 lyzed as part of a newborn screening program be used ex-
 23 cept for the strict purposes of newborn screening as au-
 24 thorized under State law or regulation.

1 **TITLE VII—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 701. NOTIFICATION OF PRIVACY OBLIGATIONS.**

4 Not less than annually, every person who maintains
5 individual DNA samples or genetic information shall no-
6 tify their employees of their responsibilities under this Act
7 and the penalties for violating the provisions of this Act.

8 **SEC. 702. TRANSFER OF OWNERSHIP, DISCONTINUANCE OF**
9 **SERVICES.**

10 (a) ACTIVITIES INVOLVING DNA SAMPLES.—Any
11 person in possession of DNA samples who intends to dis-
12 continue a program, business, enterprise, or service in
13 which such DNA samples were collected, stored, or ana-
14 lyzed or who intends to transfer control of such program,
15 business, enterprise, or service to a person who intends
16 to use such DNA samples for a substantially different pur-
17 pose than was authorized at the time of collection, storage,
18 or analysis of such DNA samples shall inform the individ-
19 ual that the individual has the right to order that the
20 records regarding such samples be returned to the individ-
21 ual.

22 (b) NO RESPONSE.—If a person to which subsection
23 (a) applies receives no response from an individual to
24 which information is provided under such subsection, the
25 person in possession of the records involved—

1 (1) in the case of discontinuance, shall destroy
2 the records, or

3 (2) in the case of an intended transfer, may
4 proceed with transfer of control of the records.

5 **TITLE VIII—ENFORCEMENT**

6 **SEC. 801. CIVIL REMEDIES.**

7 (a) PRIVATE RIGHT OF ACTION.—Any person whose
8 rights under this Act have been violated may maintain a
9 civil action for damages or equitable relief as provided for
10 in this section.

11 (b) JURISDICTION.—An action may be brought under
12 this section in the district courts of the United States or
13 a State court of competent jurisdiction.

14 (c) RELIEF.—In any action brought under this sec-
15 tion, a court may order a person to comply with the provi-
16 sions of this Act and may order any other appropriate eq-
17 uitable relief.

18 (d) LIABILITY FOR NEGLIGENT VIOLATIONS.—Any
19 person who through negligence collects, stores, or analyzes
20 a DNA sample in violation of this Act, or discloses genetic
21 information in violation of this Act, shall be liable to the
22 individual for each such violation in an amount equal to—

23 (1) any actual damages sustained as a result of
24 the collection, storage, analysis, or disclosure, or
25 \$50,000, whichever is greater;

1 (2) in any case where such violation has re-
2 sulted in profit or monetary gain, treble damages;
3 and

4 (3) in the case of a successful action to enforce
5 any liability under this section, the costs of the ac-
6 tion together with reasonable attorneys' fees as de-
7 termined by the court.

8 (e) LIABILITY FOR WILLFUL VIOLATIONS.—Any per-
9 son who—

10 (1) through a request, the use of persuasion,
11 under threat, or with a promise of reward, willfully
12 induces another to collect, store, or analyze a DNA
13 sample in violation of this Act, or disclose genetic in-
14 formation in violation of this Act, or

15 (2) willfully collects, stores, or analyzes a DNA
16 sample in violation of this Act, or willfully discloses
17 genetic information in violation of this Act, shall be
18 liable to the individual for each such violation in an
19 amount equal to—

20 (A) any actual damages sustained as a re-
21 sult of the collection, analysis, or disclosure, or
22 \$100,000, whichever is greater;

23 (B) punitive damages as the court may
24 allow; and

1 (C) in the case of a successful action under
 2 this section, the costs of the action together
 3 with reasonable attorneys' fees as determined
 4 by the court.

5 (f) STATUTE OF LIMITATIONS.—Except with respect
 6 to subsection (g), any action under this section must be
 7 brought within 6 years of the date that the alleged viola-
 8 tion was or should have been discovered.

9 (g) TOLLING OF LIMITATIONS.—If the person enti-
 10 tled to maintain an action under this section is a minor,
 11 or is incapacitated by reason of mental illness when the
 12 right to bring an action first occurs, the action may be
 13 commenced up to 10 years after the disability is removed.

14 **SEC. 802. CIVIL PENALTIES AND INJUNCTIVE RELIEF.**

15 (a) IN GENERAL.—Whenever the Attorney General
 16 has reason to believe that any person is using or is about
 17 to use any method, act or practice in violation of the provi-
 18 sions of this Act, and that proceedings would be in the
 19 public interest, the Attorney General may bring an action
 20 against such person to restrain by temporary restraining
 21 order or preliminary or permanent injunction the use of
 22 such method, act or practice.

23 (b) JURISDICTION.—The action may be brought in
 24 the district court of the jurisdiction in which the person
 25 resides or has a principal place of business.

1 (c) RELIEF.—The court may issue temporary re-
 2 straining orders or preliminary or permanent injunctions
 3 and make such other orders or judgments as may be nec-
 4 essary to prevent harm or to remedy harm suffered by
 5 any person as a result of the use or employment of such
 6 method, act or practice in violation of this Act.

7 (d) CIVIL PENALTY.—If the court finds that a person
 8 has employed any method, act or practice which the per-
 9 son knew or should have known to be in violation of this
 10 Act, the court may require such person to pay a civil pen-
 11 alty of not more than \$50,000 for each such violation and
 12 may also require such person to pay reasonable costs of
 13 investigation and litigation of such violation, including
 14 reasonable attorneys fees.

15 **TITLE IX—EFFECTIVE DATES;**
 16 **APPLICABILITY; AND RELA-**
 17 **TIONSHIP TO OTHER LAWS**

18 **SEC. 901. EFFECTIVE DATES.**

19 This Act shall take effect on January 1, 1998.

20 **SEC. 902. APPLICABILITY.**

21 (a) AUTHORIZATION FOR ANALYSIS OF DNA SAM-
 22 PLES COLLECTED PRIOR TO EFFECTIVE DATE.—In order
 23 to comply with the provisions of this Act, any person who,
 24 prior to the effective date of this Act, is in possession of
 25 a DNA sample shall, prior to performing any genetic anal-

1 ysis on the DNA samples make the disclosures required
 2 by section 101(c), and obtain a written authorization that
 3 meets the requirements of section 202.

4 (b) RESEARCH ON DNA SAMPLES COLLECTED
 5 PRIOR TO EFFECTIVE DATE.—Any person who is con-
 6 ducting research under a protocol approved by an Institu-
 7 tional Review Board may use DNA samples collected prior
 8 to the effective date of this Act for the 3-year period begin-
 9 ning on the date of enactment of this Act.

10 (c) AUTHORIZATIONS FOR DISCLOSURES.—An au-
 11 thorization for the disclosure of genetic information that
 12 is executed before January 1, 1998, and which does not
 13 meet the requirements of section 103, but which is valid
 14 under State law on January 1, 1997, shall remain valid
 15 until the expiration of 30 days after the effective date of
 16 this Act, or the expiration date specified in the authoriza-
 17 tion, whichever occurs earlier.

18 **SEC. 903. RELATIONSHIP TO OTHER LAWS.**

19 (a) IN GENERAL.—No State may establish or enforce
 20 any law or regulation concerning the collection, storage,
 21 of analysis of DNA samples except to the extent that such
 22 law or regulation—

23 (1) prohibits or further restricts the collection,
 24 storage, or analysis of DNA samples; or

1 (2) provides additional protections to the pri-
2 vacy interests of the individual who is a DNA sam-
3 ple source.

4 (b) DISCLOSURE.—No State may establish or enforce
5 any law or regulation concerning the disclosure of genetic
6 information except to the extent that such law or regula-
7 tion, with respect to the limitations contained in this
8 Act—

9 (1) prohibits or further restricts the disclosure
10 of such information;

11 (2) prohibits or further restricts the use of such
12 information; or

13 (3) provides additional protection to the privacy
14 interests of the individual who is a DNA sample
15 source or the subject of the genetic information.

16 (c) CONSTRUCTION.—Nothing in this Act shall be
17 construed as limiting or prohibiting the pursuit of any
18 other remedies available under common or statutory law
19 in regard to the collection, storage, analysis of DNA sam-
20 ples, and the disclosure of genetic information.

○